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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,282	08/23/2001	Michael J. Horzewski	9345.17121-CIP C	1930
26308	7590	11/22/2005	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			SMITH, RUTH S	
			ART UNIT	PAPER NUMBER
			3737	
DATE MAILED: 11/22/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,282	HORZEWSKI ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-31 and 33-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-31 and 33-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/02, 5/03, 10/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS filed 3/05, 8/05, 10/05</u> . |

Election/Restrictions

Applicant's election without traverse of species 2 in the reply filed on 8/22/05 is acknowledged.

Specification

The disclosure is objected to because of the following informalities: On page 1 of the specification applicant should update the status of the continuing data. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 18-31,33-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to provide any examples of agents administered to an individual that would result in a decrease in blood perfusion in the individual.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is impossible to determine the scope of the claimed invention in that claim 40 sets forth a system and further defines a system element, however, the claim depends from a method claim.

Claim Objections

Claims 18-27,29-31,33-39 are objected to because of the following informalities: In claim 19, "the heart" lacks antecedent basis. In claims 18,31, "administered" should be changed to "to be administered" so as to avoid positively setting forth the individual as part of the claimed invention. In claim 19, line 2, "an individual" should be "the individual". In claims 20,21,24, line 1 a space should be inserted between the claim number and the term "wherein". In claim 29, "the heart" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18,27,28,31,40,41 are rejected under 35 U.S.C. 102(e) as being anticipated by Fenn et al ('426). The claims are directly readable on Fenn et al which discloses administering an agent to an individual to cause a decrease in blood perfusion and applying ultrasound therapy thereafter. The ultrasound will inherently result in an increase in blood perfusion in the area treated. It should be noted that the use of ultrasound is seen in column 12. With regard to claims 27,40 any means for positioning the ultrasound applicator would include an assembly to stabilize its placement.

Claims 31,33-35,37,38,41 are rejected under 35 U.S.C. 102(e) as being anticipated by Bond et al ('502). The claims are directly readable on Bond et al which disclose administering an agent to an individual and applying ultrasound to the individual. The ultrasound will inherently affect an increase in blood perfusion. The frequency ranges disclosed by Bond et al are as set forth in the claims. Bond et al disclose that the ultrasound applicator 42 can be the one disclosed in US Patent No. 5,879,314 to Peterson et al which is incorporated by reference. The Peterson et al reference clearly sets forth the operating parameters as set forth in claim 37. The operating parameters are well known ultrasound therapy operating parameters for use on a patient without causing harm to the patient. With respect to claim 34, the transducer used would inherently have the aperture size as set forth.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19,29,30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenn et al ('426). Fenn et al disclose administering an agent to an individual to cause a decrease in blood perfusion and applying ultrasound therapy thereafter. The ultrasound will inherently result in an increase in blood perfusion in the area treated. It should be noted that the use of ultrasound is seen in column 12. Fenn et al disclose that the invention can be used to enhance radiation therapy for targeted drug delivery. Therefore, it would have been obvious to one skilled in the art to have modified Fenn et al such that it is used to apply treatment to the heart. Such a modification merely involves the selection of one known type of targeted drug delivery method and system. With respect to claim 30, the transcutaneous application of ultrasound to the body is a well known expedient in order to avoid placing an applicator inside of the patient where it can harm the patient. Therefore, it would have been obvious to one skilled in the art to have transcutaneously apply the ultrasound.

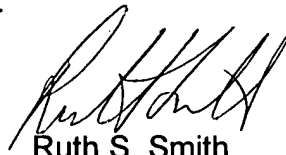
Claims 20-26,33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenn et al in view of Peterson et al ('314). Fenn et al disclose administering an agent to an individual to cause a decrease in blood perfusion and applying ultrasound therapy thereafter. The ultrasound will inherently result in an increase in blood perfusion in the area treated. It should be noted that the use of ultrasound is seen in column 12. Peterson et al disclose an ultrasound therapy system and sets forth the operating parameters as set forth in the claims. The operating parameters are well known ultrasound therapy operating parameters for use on a patient without causing harm to the patient. With respect to claims 21,34, the transducer used would inherently have the aperture size as set forth.

Claims 36,39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al ('502). Bond et al disclose administering an agent to an individual and applying ultrasound to the individual. The ultrasound will inherently affect an increase in blood perfusion. The frequency ranges disclosed by Bond et al are as set forth in the claims. With respect to claims 36,39, in the absence of any showing of criticality or unexpected result, the specific frequency selected from the range of 20KHz to 50KHz would have been obvious to one skilled in the art without undue experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS